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PTO/SB/21 (02-09)

Approved for use through 07/31/2006. OMB 0651-0081

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<b>TRANSMITTAL FORM</b> <small>(to be used for all correspondence after initial filing)</small>	Application Number	09/722,070
	Filing Date	November 24, 2000
	First Named Inventor	Kelleher
	Art Unit	3744
	Examiner Name	William Charles Doerrler
Total Number of Pages in This Submission	Attorney Docket Number	028US1

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Postcard
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<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or Individual name	Jonathan D. Spangler	
Signature		
Date	June 28, 2004	

CERTIFICATE OF TRANSMISSION/MAILING			
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Typed or printed name	Jonathan D. Spangler		
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/17 (10-03)

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

## Complete if Known

Application Number 09/722,070  
Filing Date Nov. 24, 2000  
First Named Inventor KELLEHER  
Examiner Name DOEBLER  
Art Unit 3744  
Attorney Docket No. 028051

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number  
Deposit Account Name

50-2040

NUVASIVE, INC.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	2001	770	385	Utility filing fee	
1002	2002	340	170	Design filing fee	
1003	2003	530	265	Plant filing fee	
1004	2004	770	385	Reissue filing fee	
1005	2005	160	80	Provisional filing fee	

SUBTOTAL (1) (\$)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description
1202	2202	18	9	Claims in excess of 20
1201	2201	86	43	Independent claims in excess of 3
1203	2203	290	145	Multiple dependent claim, if not paid
1204	2204	86	43	** Reissue independent claims over original patent
1205	2205	18	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	2051	130	65	Surcharge - late filing fee or oath	
1052	2052	50	25	Surcharge - late provisional filing fee or cover sheet	
1053	1053	130	130	Non-English specification	
1812	1812	2,520	2,520	For filing a request for ex parte reexamination	
1804	1804	920*	920*	Requesting publication of SIR prior to Examiner action	
1805	1805	1,840*	1,840*	Requesting publication of SIR after Examiner action	
1251	2251	110	55	Extension for reply within first month	
1252	2252	420	210	Extension for reply within second month	
1253	2253	950	475	Extension for reply within third month	
1254	2254	1,480	740	Extension for reply within fourth month	
1255	2255	2,010	1,005	Extension for reply within fifth month	
1401	2401	330	165	Notice of Appeal	165
1402	2402	330	165	Filing a brief in support of an appeal	
1403	2403	290	145	Request for oral hearing	
1451	2451	1,510	1,510	Petition to institute a public use proceeding	
1452	2452	110	55	Petition to revive - unavoidable	
1453	2453	1,330	665	Petition to revive - unintentional	
1501	2501	1,330	665	Utility issue fee (or reissue)	
1502	2502	480	240	Design issue fee	
1503	2503	640	320	Plant issue fee	
1460	1460	130	130	Petitions to the Commissioner	
1807	1807	50	50	Processing fee under 37 CFR 1.17(q)	
1806	1806	180	180	Submission of Information Disclosure Stmt	
8021	8021	40	40	Recording each patent assignment per property (times number of properties)	
1809	2809	770	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	2810	770	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	2801	770	385	Request for Continued Examination (RCE)	
1802	1802	900	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

## SUBMITTED BY

Name (Print/Type) JONATHAN SPANGLER  
Signature

Registration No. (Attorney/Agent)

40,182

(Complete if applicable)

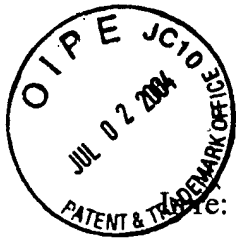
Telephone 858-243-0029

Date June 28, 2004

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PATENT  
Application Serial No. 09/722,070  
Attorney Ref. No. 028US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Patent Application of )

Brian S. Kelleher et al. )

Group Art Unit: 3744 )

App. Ser. No. 09/722,070 )

Filed: November 24, 2000 )

Examiner: William Charles Doerrler )

For: ELECTROMYOGRAPHY SYSTEM )

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop: Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 28, 2004:

Signature: \_\_\_\_\_

Printed Name: Jonathan D. Spangler

**APPEAL BRIEF UNDER 37 CFR 1.192**

Mail Stop: Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby submit an original and two copies of this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Final Office Action dated October 21, 2003.

This submission is timely, falling within two (2) months from April 26, 2004, the date the Notice of Appeal was received by the Patent Office.

A Fee Transmittal is submitted herewith authorizing payment of \$165 under 37 CFR

1.17(c) for filing this Appeal Brief from Deposit Account No. 50-2040 in the name of NuVasive,

Inc. Should any additional fees under 37 CFR 1.16 to 1.21 be required for any reason relating to the enclosed material, or should an overpayment be included herein, the Commissioner is hereby authorized to deduct or credit said fees from this Deposit Account No. 50-2040 in the name of NuVasive, Inc.

**1. Real Party in Interest**

NuVasive, Inc, assignee of the present patent application (recorded at Reel/Frame 011853/0233), is the real party in interest in this appeal. NuVasive, Inc. is a publicly traded corporation having a principal place of business at 10065 Old Grove Road, San Diego, CA 92131.

**2. Related Appeals and Interferences**

There are no related appeals or interferences know to Applicants at this time.

**3. Status of Claims**

Claims 15-16, 22-26 and 30-40 are pending in this application. Claims 15-16, 22-26 and 30-39 were rejected as of the Final Office Action. Claim 40 was inadvertently omitted from consideration in the Final Office Action, although it was listed as "Rejected" in the Advisory Action mailed May 27, 2004. Claims 15-16, 22-26 and 30-40 are currently on appeal.

**4. Status of Amendments**

A Request for Reconsideration was filed on April 21, 2004 responding to the Final Office Action mailed October 21, 2003. In an Advisory Action mailed May 27, 2004, the Examiner

asserted that the Request for Reconsideration did not place the application in condition for allowance, citing the following reason: "Approaching a spinal nerve from a lateral direction is seen as obvious in light of the cited references."

## **5. Summary of the Invention**

The present invention, as claimed, is directed to a method for detecting the presence of a nerve adjacent the distal end of at least one probe or surgical tool 20, 22. (*Fig. 1; Page 2, Lines 19-20; Page 10, Lines 3-4*). The at least one probe or tool 20, 22 may be any manner of surgical tool (*Page 10, Lines 3-4 & 10-11; Page 16, Lines 16-18*) and is provided with at least one electrode 21, 23 (*Fig. 1; Page 16, Lines 23-24*). Nerve detection is performed as the probe or surgical tool 20, 22 is advanced towards a spinal operative site (*Figs. 1, 4, 5; Page 7, Lines 12-13; Page 12, Lines 1-6; Page 16, Lines 9-10*). This is accomplished by emitting a stimulus pulse from the at least one electrode 21, 23 (*Figs. 1-3; Page 16, Lines 28-30; Page 17, Lines 11-14*), detecting the neuro-muscular responses to the stimulus pulse in at least one of a plurality of spinal nerves (*Figs. 1, 5, 6; Page 17, Lines 8-10*), and concluding that the electrode 21, 23 disposed on the probe or surgical tool 20, 22 is positioned adjacent to a first spinal nerve when the neuro-muscular response detected in the first spinal nerve is detected as a current intensity level less than or equal to a neuro-muscular response signifying close proximity to the first spinal nerve (*Figs. 1, 4; Page 17, Lines 18-22*). According to the present invention, as claimed, this process of nerve detection takes place as the at least one probe or surgical tool 20, 22 is introduced towards the patient's spine from a generally lateral direction. (*Figs. 1, 3; Page 11, Lines 19-20; Page 16, Lines 10-11*).

## **6. Issues:**

A. Whether claims 15-16, 22-26, 30-31 and 33-40 are unpatentable under 35 USC 103(a) over US Patent No. 5,775,331 to Raymond et al. ("Raymond '331") in view of US Patent No. 6,027,456 to Feler et al. ("Feler '456").

B. Whether claims 15-16, 22-26, 30-31 and 33-40 are unpatentable under 35 USC 103(a) over US Patent No. 5,284,153 to Raymond et al. ("Raymond '153") or US Patent No. 5,284,154 to Raymond et al. ("Raymond '154") in view of Feeler '456.

C. Whether claims 15-16, 22-26, 30, 32-33 and 35 are unpatentable under 35 USC 103(a) over US Patent No. 5,830,151 to Hadzic et al. ("Hadzic '151") in view of Feeler '456.

**7. Grouping of the Claims:**

Claims 15-16, 22-26 and 30-40 stand or fall together.

**8. Argument:**

*A. Raymond '331 in view of Feler '456 fail to render obvious claims 15-16, 22-26, 30-31 and 33-40.*

Applicants respectfully appeal the decision of the Examiner in the Final Office Action (rejecting claims 15-16, 22-26, 30-31 and 33-40 as being unpatentable over Raymond '331 in view of Feler '456) and respectfully request an indication of allowance for the following reasons.

Claim 15 on appeal recites "A method for detecting the presence of a nerve adjacent the distal end of at least one probe or surgical tool, comprising: (a) emitting a stimulus pulse from an electrode disposed on a probe or surgical tool as said probe or tool is introduced towards the patient's spine from a generally lateral direction; (b) detecting neuro-muscular responses to the stimulus pulse in at least one of a plurality of spinal nerves; and (c) concluding that the electrode

disposed on the probe or surgical tool is positioned adjacent to a first spinal nerve when the neuro-muscular response detected in the first spinal nerve is detected as a current intensity level less than or equal to a neuro-muscular response signifying close proximity to the first spinal nerve.”

While Raymond ‘331 and Feler ‘456 are generally relevant to identifying the location of nerves, neither of these references appear to disclose or motivate (among other things) the claimed feature of identifying the location of nerves as a probe or surgical tool is introduced towards a patient’s spine from a generally lateral direction as set forth in Claim 15. On Pages 4-5 of the Final Office Action (under “Response to Arguments”), the Examiner addressed the “generally lateral direction” claim language, deeming Applicants’ arguments unpersuasive by asserting that the probe or surgical tool must approach the nerve from the lateral approach. Applicants respectfully attempted to correct the Examiner’s misreading of claim 15 in the Request for Reconsideration, by pointing out that the claimed invention is directed at performing nerve detection as a probe or surgical tool is advanced towards a patient’s *spine* in a *generally lateral direction*, as opposed to an actual spinal *nerve* (as asserted by the Examiner). On the Continuation Sheet of the Advisory Action, the Examiner responded by ignoring this distinction and simply repeating his previous reason for rejection: “Approaching a spinal *nerve* from a lateral direction is seen as obvious in light of the cited references.” (Emphasis added).

Applicants respectfully assert that the Examiner erred by mischaracterizing (or simply misreading) the claim language of Claim 15, which in relevant part reads: “emitting a stimulus pulse from an electrode disposed on a probe or surgical tool *as said probe or tool is introduced*

*towards the patient's spine from a generally lateral direction.*" (Emphasis added). More specifically, the claim language of Claim 15 did not – as asserted in the Final Office Action – indicate that the probe or tool was introduced towards the patient's spinal nerves. While it may be true that a probe must approach a nerve from a lateral direction (if you treat the nerve as a line, as suggested in the Final Office Action), the same is not true of the approach to the patient's spine. Indeed, a patient's spine can be approached through any number of different directions, including generally posteriorly (such as by making an incision in the posterior region or "back" of the patient), generally anteriorly (such as by making an incision in the anterior region or "front" of the patient), and – as set forth in Claim 15 – generally laterally (such as by making an incision in the side or lateral region of the patient). This feature of Claim 15 is supported, by way of example, with reference to FIGS. 1 and 4 in the present application, wherein probe or tools 20, 22 are shown being advanced toward the patient's spine in a generally lateral direction.

The Raymond '331 and Feler '456 references (along with the other references of in the record) appear to be silent with regard to (among other things) the feature of detecting the presence of nerves while approaching a patient's spine from a generally lateral direction as set forth in Claim 15. Given this, Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as set forth in Claim 15) after consulting with the cited references. As such, Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 15. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.



Claims 16, 22-26, 30-31, and 33-40, being dependant upon and further limiting independent claim 15, should be allowed for the reason set forth in support of the allowability of claim 15, as well as the additional limitations they contain.

***B. Raymond '153 or '154 in view of Feler '456 fail to render obvious claims 15-16, 22-26, 30-31 and 33-40.***

Applicants respectfully appeal the decision of the Examiner in the Final Office Action (rejecting claims 15-16, 22-26, 30-31 and 33-40 as being unpatentable over Raymond '153 or '154 in view of Feler '456) and respectfully request an indication of allowance for the following reasons.

While Raymond '153, Raymond '154 and Feler '456 are generally relevant to identifying the location of nerves, none of these references appear to disclose or motivate (among other things) the claimed feature of identifying the location of nerves as a probe or surgical tool is introduced towards a patient's spine from a generally lateral direction as set forth in Claim 15. As noted above, this claimed feature was apparently missed by the Examiner, who asserted in the Final Office Action that the probe or tool was introduced towards the patient's spinal nerves. Again, this is a significant distinction a patient's spine can be approached through any number of different directions, including generally posteriorly (such as by making an incision in the posterior region or "back" of the patient), generally anteriorly (such as by making an incision in the anterior region or "front" of the patient), and – as set forth in Claim 15 – generally laterally (such as by making an incision in the side or lateral region of the patient).

The Raymond '153, Raymond '154 and Feler '456 references (along with the other references of in the record) appear to be silent with regard to (among other things) the feature of detecting the presence of nerves while approaching a patient's spine from a generally lateral direction as set forth in Claim 15. Given this, Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as set forth in Claim 15) after consulting with the cited references. As such, Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 15. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 16, 22-26, 30-31, and 33-40, being dependant upon and further limiting independent claim 15, should be allowed for the reason set forth in support of the allowability of claim 15, as wall as the additional limitations they contain.

***C. Hadzic '151 in view of Feler '456 fail to render obvious claims 15-16, 22-26, 30, 32-33 and 35.***

Applicants respectfully appeal the decision of the Examiner in the Final Office Action (rejecting claims 15-16, 22-26, 30, 32-33 and 35 as being unpatentable over Hadzic '151 in view of Feler '456) and respectfully request an indication of allowance for the following reasons.

While Hadzic '151 and Feler '456 are generally relevant to identifying the location of nerves, none of these references appear to disclose or motivate (among other things) the claimed feature of identifying the location of nerves as a probe or surgical tool is introduced towards a patient's spine from a generally lateral direction as set forth in Claim 15. As set forth above, in both the Final Office Action and Advisory Action, the Examiner incorrectly focused on the patient's spinal nerves as opposed to the actual claim language, which clearly specifies that the present invention involves performing nerve detection as the "probe or tool is advanced towards a patient's *spine* from a generally lateral direction." As noted above, a patient's spine can be approached through any number of different directions, including generally posteriorly (such as by making an incision in the posterior region or "back" of the patient), generally anteriorly (such as by making an incision in the anterior region or "front" of the patient), and – as set forth in Claim 15 – generally laterally (such as by making an incision in the side or lateral region of the patient).

The Hadzic '151 and Feler '456 references (along with the other references of in the record) appear to be silent with regard to (among other things) the feature of detecting the presence of nerves while approaching a patient's spine from a generally lateral direction as set forth in Claim 15. Given this, Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as set forth in Claim 15) after consulting with the cited references. As such, Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim

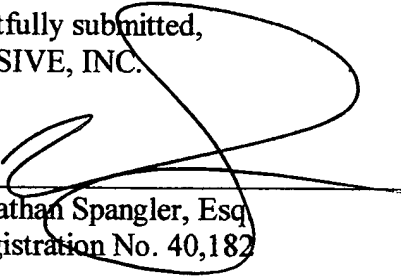
15. Claim 15 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 16, 22-26, 30, 32-33 and 35, being dependant upon and further limiting independent claim 15, should be allowed for the reason set forth in support of the allowability of claim 15, as well as the additional limitations they contain.

**CONCLUSION**

As demonstrated above, the Raymond '331, Raymond '153, Raymond '154, Feler '456 and/or Hadzic '151 fail to render obvious claims 15-16, 22-26 and 30-40 now before the Board. Applicants respectfully request favorable consideration and allowance of claims 15-16, 22-26 and 30-40.

Respectfully submitted,  
NUVASIVE, INC.

By:   
Jonathan Spangler, Esq.  
Registration No. 40,182

10065 Old Grove Road  
San Diego, CA 92131  
Tel.: (858) 243-0029

Date: June 28, 2004

**9. Appendix of Claims Pending**

15. (Previously Presented) A method for detecting the presence of a nerve adjacent the distal end of at least one probe or surgical tool, comprising:

- (a) emitting a stimulus pulse from an electrode disposed on a probe or surgical tool as said probe or tool is introduced towards the patient's spine from a generally lateral direction;
- (b) detecting neuro-muscular responses to the stimulus pulse in at least one of a plurality of spinal nerves; and
- (c) concluding that the electrode disposed on the probe or surgical tool is positioned adjacent to a first spinal nerve when the neuro-muscular response detected in the first spinal nerve is detected as a current intensity level less than or equal to a neuro-muscular response signifying close proximity to the first spinal nerve.

16. (Original) The method of claim 15, wherein the stimulus pulse is emitted from an electrode disposed on the distal end of the at least one probe or surgical tool.

22. (Original) The method of claim 15, wherein, detecting neuro-muscular responses to the stimulus pulse in each of the plurality of spinal nerves comprises:

detecting the neuro-muscular responses at a plurality of distally spaced apart myotome locations corresponding to each of the spinal nerves.

23. (Original) The method of claim 15, further comprising:  
repeating the method of claim 15, while the current intensity level of the electrical stimulus pulse is varied over time.

24. (Original) The method of claim 23, wherein the current intensity level of the stimulus pulse is varied incrementally.

25. (Previously Presented) The method of at least one of claims 23 and 24, wherein the current intensity level of the stimulus pulse is increased over time.

26. (Original) The method of claim 15, wherein, the plurality of spinal nerves comprise: nerves exiting from successive vertebrae.
30. (Original) The method of claim 15, wherein the method of claim 1 is performed in a repeating sequence.
31. (Original) The method of claim 15, wherein the method of claim 1 is repeated automatically.
32. (Original) The method of claim 30, wherein the method of claim 15 is repeated under operator control.
33. (Original) The method of claim 15, further comprising:  
visually indicating to an operator the current intensity of the stimulus pulse which elicits a neuro-muscular response in each of the plurality of spinal nerves.
34. (Original) The method of claim 33, further comprising:  
repeating the method of claim 15, thereby detecting and measuring sequential sets of neuro-muscular responses for each of the plurality of spinal nerves; and  
simultaneously visually displaying to an operator the measured levels of at least two sets of the neuro-muscular responses for each of the plurality of spinal nerves.
35. (Previously Presented) The method of claim 15, further comprising:  
visually indicating to an operator that a spinal nerve is positioned near the distal end of the at least one probe or surgical tool.
36. (Previously Presented) The method of claim 15, further comprising:  
audibly indicating to an operator that a spinal nerve is positioned near the distal end of the at least one probe or surgical tool.

37. (Original) The method of claim 36, wherein audibly indicating comprises:  
sounding an alarm as the nerve is approached.

38. (Original) The method of claim 36, further comprising:  
varying the volume of the alarm as the nerve is approached.

39. (Original) The method of claim 37, further comprising:  
varying the frequency of the alarm as the nerve is approached.

40. (Previously Presented) The method of claim 15, wherein the at least one probe or  
surgical tool comprises:

at least one probe or surgical tool dimensioned to be introduced generally laterally  
towards the patient's spine.